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Subject: OCSPP News for December 15, 2020

OCSP News Round-Up

Toxics

- Chemical Watch 12/15; [US EPA concludes Perc poses unreasonable risk for most uses](#)
- Happi 12/15; [Trade Groups Applaud EPA's 1,4-Dioxane Assessment](#)
- Bloomberg Law 12/14; [All Sides Blast EPA for Latest Conclusions on Toxic Solvent](#)
- Bloomberg Law 12/14; [EPA to Restrict Solvent Used in Dry Cleaning, Coolant Production](#)
- Bloomberg Law 12/14; [Imerys \\$4 Million Punitive Award Upheld in Asbestos-in-Talc Case](#)
- Inside TSCA 12/14; [EPA Expands Risk Findings That Must Be Regulated In Final Perc Evaluation](#)
- Inside TSCA 12/14; [EPA faces more suits over HBCD evaluation](#)
- Cape Cod.com 12/13; [Breast Cancer Coalition Addresses Dangers of PFAS Chemicals](#)

Pesticides

- AGWeek 12/15; [Ag Week: Minnesota sets June 30 cutoff date for dicamba, will follow federal registration label usage](#)
- The Hill 12/15; [Trump administration punts on protections for monarch butterfly](#)
- E&E News 12/15; ['Habitat' defines a heated new debate over protections](#)

Blog/OpEd/Other

- JD Supra (Kelley Drye & Warren LLC) 12/14; [Cleaning Product Enforcement Challenge Highlights Reach of EPA's Antimicrobial Regulatory Authority](#)
- The National Law Review (Bergeson & Campbell) 12/14; [EPA Publishes Draft Compliance Guide Addressing Surface Coatings under PFAS SNUR](#)
- Bergeson & Campbell TSCA Blog 12/15; [EPA Releases Final Risk Evaluation for Perchloroethylene, Finds Almost All Conditions of Use Present Unreasonable Risks to Workers, ONUs, Consumers, and Bystanders](#)
- NRDC Blog 12/15; [Monarch Butterflies Struggle as Feds Delay Protection](#)

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US EPA concludes Perc poses unreasonable risk for most uses

Terry Hyland, Chemical Watch

<https://chemicalwatch.com/192438/us-epa-concludes-perc-poses-unreasonable-risk-for-most-uses>

The US EPA has concluded that perchloroethylene (Perc) poses an unreasonable risk to workers, occupational non-users, bystanders and consumers in all but two of 61 conditions of use (CoUs) evaluated.

The final TSCA risk evaluation generally follows the findings of the [draft evaluation](#) released in the spring, but with a few notable changes. It combined a number of commercial and industrial uses into single categories, reducing the total number of CoUs reviewed from 69 to 61. It also added a handful of commercial and consumer applications to the list of those that present unreasonable risks that were previously found not to do so, including consumer uses of livestock grooming adhesives, aerosol coatings and primers and metallic overglazes.

Overall, the agency said it found unreasonable risks for 59 out of 61 total CoUs reviewed across manufacturing, processing, industrial and commercial uses, as well as consumer and disposal activities.

It now has one year to propose regulatory action to mitigate those risks, with a final rule due in December 2022. Conditions of use found to present an unreasonable risk include:

- domestic manufacture and import;
- seven processing uses, such as when used as an intermediate or incorporated into cleaning and degreasing or paint and coating products;
- 30 industrial and commercial uses, including as a solvent for vapour degreasing, cold cleaning, dry cleaning, petrochemical manufacturing, and in inks and their removal products;
- 19 consumer uses, including in dry cleaning, lubricants and greases, and in adhesives for arts and crafts; and
- disposal.

The final risk evaluation also added the US Defense Department's use of Perc for oil analysis and water pipe repair as a CoU presenting an unreasonable risk.

Only the substance's distribution in commerce and uses in industrial and commercial lubricants, such as for cutting tool coolants, were not found to do so, the EPA said.

Note of caution

In the meantime, the EPA "strongly" recommended that users of Perc or items containing it follow all labelling and safety data sheet (SDS) instructions.

The agency also said consumers wishing to avoid exposure should ask retailers if their products contain the solvent, which is used in several consumer applications, including in adhesives for arts and crafts, livestock grooming, stone and steel polishes and wipe cleaners.

Perc, also known as tetrachloroethylene or PCE, has a variety of industrial uses, including in the production of fluorinated compounds and as a solvent in dry cleaning and vapour degreasing.

On the risk evaluation page, the agency acknowledged consumers' potential concern over its use in dry cleaning. They can limit their exposure by reducing how much they wear "articles that have been very recently dry cleaned", it said.

But the EPA did not make findings of any unreasonable risks to the environment. Previously, in its draft evaluation, it had preliminarily found such risks to aquatic organisms.

It reached that conclusion despite questions from several members of the agency's Scientific Advisory Committee on Chemicals (Sacc), who said in an [August peer review](#) that the draft hadn't gone far enough.

The TSCA review for Perc is the sixth to be finalised out of the [first ten](#) existing chemicals subject to risk evaluation under the amended law. The agency has also released those for:

- [methylene chloride](#);

- 1-bromopropane;
- cyclic aliphatic bromide cluster (HBCD);
- carbon tetrachloride; and
- trichloroethylene (TCE).

Trade Groups Applaud EPA's 1,4-Dioxane Assessment

Happi Staff, Happi

https://www.happi.com/contents/view_breaking-news/2020-12-14/trade-groups-applaud-epas-14-dioxane-assessment/

The American Cleaning Institute (ACI) and Household & Commercial Products Association (HCPA) support a recent determination by the US Environmental Protection Agency (EPA) that certain consumer products containing the by-product 1,4-dioxane do not present an unreasonable risk of injury to human health or the environment.

On December 10, ACI and HCPA submitted comments and data to the EPA on 1,4-Dioxane; Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA) Risk Evaluation.

These comments came in response to EPA's issuance of a supplemental draft risk evaluation of 1,4-dioxane, which found that regular use of surface cleaning, laundry, dishwashing and, general purpose cleaning products does not pose an unreasonable risk to consumers. In the comments, the associations specifically:

- Highlight that the data provided demonstrates much lower levels, reflective of current concentrations in products.
- Draw attention to an industry effort to develop, optimize, and validate a method to measure 1,4-dioxane to very low concentrations in complex formulations.
- Recommend that EPA's risk evaluation of 1,4-dioxane include other use scenarios, including consumer all-purpose cleaners, commercial cleaning products, and general population exposures from drinking water.

"ACI and HCPA support the EPA's efforts to elicit additional public comment on the draft assessment of the potential risk of 1,4-dioxane in consumer products," said Kathleen Stanton, ACI associate vice president-technical & international affairs, and Dr. Steve Bennett, HCPA senior vice president, scientific & regulatory affairs. "Companies invest significant time and resources to formulate products responsibly, and we are pleased to see that the Agency agrees that the conditions of use they evaluated do not present an unreasonable risk."

1,4-dioxane is a byproduct of the manufacturing process for cleaning products and detergents and is not an intentionally added ingredient. Companies continue to work diligently to adjust manufacturing processes to remove the trace amounts that have been found in these products. Read the associations' complete comments here.

All Sides Blast EPA for Latest Conclusions on Toxic Solvent

Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/all-sides-blast-epa-for-latest-conclusions-on-toxic-solvent>

Environmentalists, industry groups, and 16 attorneys general are among those criticizing the EPA for its latest analysis of the toxic solvent 1,4-dioxane, saying the agency's conclusions of its risk are fundamentally flawed.

The criticism came in more than a dozen comments that the Environmental Protection Agency posted Monday about its extra analysis of 1,4-dioxane. The agency agreed to examine more exposures to 1,4-dioxane—used to make adhesives, sealants, spray polyurethane foam, among other products—at the request of several trade groups following the release of a draft risk analysis.

The American Chemistry Council, which represents chemical makers, said it was "deeply troubled" by the EPA's follow-up findings. Nonprofit organizations also blasted the EPA's analysis for many reasons. Attorneys general from 15 states, the District of Columbia, and New York City's corporation counsel, meanwhile, faulted findings in the agency's original and supplemental analyses.

"Left uncorrected, the deficiencies in the draft evaluation will fatally compromise the agency's final risk evaluation and any subsequent risk management of 1,4-dioxane, and fail to protect human health and the environment," the group of attorneys general wrote.

The supplemental analysis studied the risks of 1,4-dioxane in consumer products, which the first study overlooked. The agency concluded the chemical poses too little risk to consumers to require agency regulation, but it found lower doses of the chemical could cause potential liver or kidney function damage, a concern that workers producing, mixing, and using the chemical could face.

The EPA also studied 1,4-dioxane in lakes and other recreational bodies of water in the supplemental analysis and concluded too little public health risk existed to require regulation.

'Significant Changes'

The American Chemistry Council and other industry groups supported the EPA's conclusion that 1,4-dioxane posed no unreasonable risk to consumers. But it faulted other parts of the report.

"We are deeply troubled, however, by the significant changes to the evaluation of chronic human health hazards resulting from dermal exposure presented in the draft supplement," Stephen P. Risotto, a senior director at the trade association, wrote.

While 1,4-dioxane is primarily an industrial chemical, trace amounts are found in cosmetics, and personal care and cleaning products because it's a byproduct of ingredients in those products.

A coalition of environmental and labor groups represented by Earthjustice and the Occupational Safety & Health Law Project wrote that by "ignoring the groups that are the most exposed and the most susceptible to that chemical's serious health effects, EPA violates the law and leaves millions of people at risk."

The EPA disregarded a request by several groups to evaluate the health effects of 1,4-dioxane in drinking water. The American Cleaning Institute and the Household & Commercial Products Association had asked the agency to expand its analysis to include even more consumer uses and 1,4-dioxane's presence in drinking water.

Some states don't have the resources to conduct such analyses, and limits in 17 states on groundwater or drinking water standards or guidelines range from 0.3 to 77 parts per billion, said the Association of State Drinking Water Administrators, which represents public drinking water utilities and also asked for a drinking water analysis.

"Preventing contaminants from entering drinking water sources is more effective and less expensive than having to remove them once drinking water has become contaminated," the water association wrote.

The 1,4-dioxane risk evaluation is one of 10 analyses the EPA has worked towards issuing as final by year's end. The agency has issued conclusions for six of those 10 chemicals.

EPA to Restrict Solvent Used in Dry Cleaning, Coolant Production

Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/epa-to-restrict-solvent-used-in-dry-cleaning-coolant-production>

A solvent used to dry clean clothes, make refrigerants, and clean industrial and household equipment must be regulated because it has too much chance of making people sick, the EPA said Monday.

The Environmental Protection Agency released its final conclusions about the risks of perchloroethylene. Numerous industries and consumers use the solvent to clean an array of products, and it also is used to make other industrial products and chemicals.

The EPA concluded 59 of 61 ways people could be exposed to perchloroethylene pose an unreasonable risk of increasing cancer or spurring a range of nervous system problems, including headaches, confusion, and weakness.

Workers using the solvent, and individuals near them, faced risks of both cancer and nervous systems problems, while consumers using a perchloroethylene-containing product and people near them faced too much chance of nervous system problems, the agency said in its final conclusion.

Perchloroethylene also poses no undue risks to the environment, including aquatic animals, the EPA concluded, reversing the findings in its draft analysis.

Next Steps

The EPA now must begin immediately developing restrictions for the solvent and propose them within one year. Typically, the agency invites all interested parties to a virtual public meeting within weeks after it concludes a chemical in commerce poses unreasonable risks.

The agency didn't examine what, if any, health risks the solvent may pose to the general population, including people living near dry cleaners or hazardous waste sites where it's a frequent contaminant. The agency's policy is to presume air, waste, and other regulations adequately address those risks.

Companies that produced or imported perchloroethylene between 2012 and 2015 included the Axiall Corp., now part of the Westlake Chemical Corp.; Occidental Chemical Holding Corp.; the Olin Corp.; and Superior Oil Co. Inc. The yearly national production volume ranged from 324 million to 388 million pounds during those years—the most recent for which the EPA has information.

Primary users of perchloroethylene are business that make refrigerants that substitute for ozone-depleting chemicals. Dry cleaners are the second largest users. An array of industries use it to clean equipment and make products such as adhesives, brake cleaners, and lubricants.

The solvent, which goes by many names, typically is identified on business documents by its Chemical Abstracts Service number (CAS No. 127-18-4).

Imerys \$4 Million Punitive Award Upheld in Asbestos-in-Talc Case

David McAfee, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/imerys-4-million-punitive-award-upheld-in-asbestos-in-talc-case>

Imerys Talc America Inc. failed to convince a California appeals court to overturn its share of a \$22 million judgment stemming from a lawsuit brought by a man diagnosed with mesothelioma after years of working for a paint manufacturer mixing talc.

Richard Booker, who worked for Dexter Midland Chemical Company from 1970 to 1992, sued Imerys and others for personal injury and loss of consortium after being diagnosed with mesothelioma in 2015. Booker died from the disease in June 2016, and his wife Cheryl Booker added wrongful death claims and additional plaintiffs to the suit.

A jury found Imerys and another company, Vanderbilt Minerals LLC, liable for increasing Booker's risk of mesothelioma, and assigned 40% of the liability to Imerys. The jury awarded plaintiffs \$440,000 in economic damages and more than \$17 million in noneconomic damages. It also added a \$4.6 million punitive damages award against Imerys alone, finding that the company had acted with "malice, fraud, or oppression." Vanderbilt settled prior to the punitive damages phase of the trial.

The court of appeals affirmed the judgment, rejecting Imerys' argument that the evidence was insufficient as a matter of law to prove that Booker was exposed to asbestos-contaminated talc supplied by its predecessor, Cyprus Mines.

The plaintiffs submitted supporting deposition testimony and other documents of Booker's exposure, the appeals court held.

"Here, there is substantial evidence in the record of Booker's daily, long-term exposure to Cyprus talc products," the Dec. 11 opinion said. "Substantial evidence also supported the jury's finding that these Cyprus talc products were more likely than not contaminated with asbestos at the time Booker used them."

The appeals court also concluded that "substantial evidence supported a reasonable medical probability of causation" between Booker's illness and his exposure to Cyprus products.

The court rejected Imerys' argument that the trial court erred in refusing to list additional entities, including Pfizer Inc., on the special verdict form. Those entities were properly excluded because there was no substantial evidence that Booker was exposed to their asbestos-contaminated products, the appellate court concluded.

Plaintiffs are represented by Kazan Law. Imerys is represented by Dentons.

Justice Carin T. Fujisaki wrote the opinion in which Presiding Justice Peter J. Siggins and Justice Teri L. Jackson concurred.

The case is Booker v. Imerys Talc Am. Inc., Cal. Ct. App., 1st Dist., No. A153835, 12/11/20.

EPA Expands Risk Findings That Must Be Regulated In Final Perc Evaluation

Maria Hegstad, Inside TSCA

<https://insideepa.com/tsc-news/epa-expands-risk-findings-must-be-regulated-final-perc-evaluation>

EPA's just-released final evaluation of the common solvent perchloroethylene (perc or PCE) expands the number of evaluated uses the agency had initially proposed as posing unreasonable risks that must be regulated despite declining calls from advisors and environmentalists to consider risks to the general population and those from legacy uses.

EPA Dec. 14 released its final Toxic Substances Control Act (TSCA) evaluation of perc, concluding that 59 of 61 evaluated conditions of use pose unreasonable risks to workers, consumers or bystanders. The evaluation finds no unreasonable risks to the environment.

The final perc evaluation -- the sixth of the first batch of 10 the agency plans to complete before the end of the year -- finds "unreasonable risks to workers and occupational non-users (ONUs) when domestically manufacturing or importing the chemical; processing the chemical for a variety of uses; and when used in a variety of industrial and commercial applications," EPA's non-technical summary states.

"This also includes unreasonable risks to consumers from all consumer uses, and when exposed to dry cleaned articles, and to bystanders for most consumer uses."

These risks were associated with health effects including "neurotoxicity from acute exposures and neurotoxicity, kidney, liver, and immune, and developmental effects, and liver cancer from chronic exposures."

The specific uses associated with these risks "include domestic manufacturing and import; processing as a reactant or intermediate and incorporation into a formulation, mixture or reaction product; repackaging and recycling; a variety of industrial and commercial uses, including several types of degreasing uses, lubricants, adhesives, paints and coatings, automotive care products, metal and stone polishes, welding, textile processing, use in wood furniture manufacturing, foundry application, use by Department of Defense for oil analysis and water pipe repair, and various dry cleaning-related uses; and all consumer uses including exposure to dry cleaned articles."

In reaching these findings, EPA finds more uses present unreasonable risk than it did in its draft perc evaluation, released last April for peer review and public comment. The draft evaluation identified eight uses that it deemed not to present unreasonable risk.

The final evaluation narrows those uses that do not require regulation to just two: distribution in commerce and “industrial and commercial use in lubricants and greases as solvent for penetrating lubricants and cutting tool coolants.”

But EPA did not agree to concerns from science advisors who peer reviewed the draft evaluation last summer and environmentalists who argued that the agency needed to include legacy uses of perc in the evaluation and consider general population risks, such as ambient air exposure to perc releases from dry cleaning facilities that use the chemical.

Legacy Uses

In its final report issued last August, EPA’s Science Advisory Committee on Chemicals (SACC) urged the agency to evaluate risks of legacy uses of perc, joining similar calls from environmentalists. “Though releases of PCE from these legacy uses occurred in the past, exposures from these uses are ongoing and will influence both human and environmental risk now and in the future,” the SACC said.

But EPA argues that there are no legacy uses of perc that require evaluation.

In its response to comments document, the agency references the U.S. Court of Appeals for the 9th Circuit’s November 2019 decision in *Safer Chemicals, Healthy Families v. EPA* that reviewed EPA’s risk evaluation rule, one of a handful of framework-implementing rules the Trump EPA finalized after Congress rewrote TSCA in 2016. The court ruled that EPA’s risk evaluation rule unlawfully allowed the agency to exclude legacy uses from its evaluations, leading EPA to consider legacy uses for asbestos, another of the first 10 existing chemicals it chose to evaluate following the 2016 reform.

But for perc, “EPA did not identify any ‘legacy uses’ (i.e., circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) or ‘associated disposal’ (i.e., future disposal from legacy uses) of PCE, as those terms are described in EPA’s Risk Evaluation Rule, 82 FR 33726, 33729 (July 20, 2017),” the agency states in its response document.

“Therefore, no such uses or disposals were added to the scope of the risk evaluation for PCE following the issuance of the opinion in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). EPA did not evaluate ‘legacy disposal’ (i.e., disposals that have already occurred) in the risk evaluation, because legacy disposal is not a ‘condition of use’ under *Safer Chemicals*.”

EPA also held its ground in its argument that it does not need to evaluate general population exposures and risks in the perc evaluation because those exposures are already addressed by other rules and statutes -- a general, controversial policy the Trump EPA has held throughout its first evaluations despite calls from SACC to review general population exposures.

“General population exposures to PCE may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use,” the agency said.

But it noted that during the course of the risk evaluation process, Office of Pollution Prevention and Toxics (OPPT) staff worked closely with other EPA offices that regulate the chemicals’ releases under other major environmental statutes.

“Through this intra-agency coordination, EPA determined that PCE exposures to the general population via surface water, drinking water, ambient air and sediment pathways fall under the jurisdiction of other environmental statutes administered by EPA,” EPA states in the final evaluation.

The agency argued that it is “both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA.”

"EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a 'gap-filling' statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations," the document states.

EPA added that it did not evaluate hazards or exposures to the general population, "and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to the general population."

SACC, in its August report, "unanimously recommended that inhalation and dermal consumer exposures should be aggregated, and that consideration should be given to incorporation of general population exposures. This would likely increase total exposure by all routes."

EPA faces more suits over HBCD evaluation

Inside TSCA

<https://insideepa.com/tsca-takes/epa-faces-more-suits-over-hbcd-evaluation>

Labor, environmental and other groups have filed additional challenges over EPA's final TSCA evaluation of hexabromocyclododecane (HBCD) and other flame retardant chemicals, petitions that are likely to be consolidated with an existing suit filed by an Alaska group that claims it fails to adequately assess risks faced by susceptible populations.

Earthjustice, on behalf of California Professional Firefighters, California Communities Against Toxics, the Learning Disabilities Association of America, and the Sierra Club, Dec. 8 petitioned the U.S. Court of Appeals for the 9th Circuit to review EPA's evaluation of HBCD, the third of the first 10 chemicals the agency has evaluated under the Toxic Substances Control Act (TSCA) and the third to draw a lawsuit from environmentalists.

Additionally, the OSH Law Project filed a Dec. 3 petition for review on behalf of United Auto Workers (UAW) in the U.S. Court of Appeals for the District of Columbia Circuit.

The new petitions will likely be consolidated with an earlier petition for review that Earthjustice filed in the 9th Circuit in October on behalf of the Alaska Community Action on Toxics (ACCT). The petitioner Dec. 2 requested -- and won -- an extension until Feb. 3, 2021 to file its opening brief.

Neither of the new petitions provide details of their specific concerns with EPA's HBCD evaluation. UAW's petition states that it "petitions for review of a final risk evaluation and order by [EPA], determining that the chemicals in the [HBCD cluster] do not present an unreasonable risk of injury to health or the environment under certain conditions of use."

But Earthjustice issued a press release after filing ACCT's petition last October, charging that the HBCD evaluation violates requirements in the revised Toxic Substances Control Act (TSCA) because it precludes exposures from ongoing disposal of building insulation that contains the chemical, ignored exposures faced by susceptible subpopulations and failed to assess risks faced by firefighters who may be exposed to the chemicals.

"EPA's violations of the statute and consequent underestimation of the risk of HBCD means that EPA will be able to issue weaker regulations than if it had properly assessed risk," Erin Fitzgerald, press secretary at Earthjustice, said in the Oct. 19 press release.

"We're hoping the challenge would force the EPA to correct these flaws, properly assess the risk, and would result in stronger, more protective regulations."

EPA's Sept. 24 final evaluation found that six of 12 uses of HBCD and other chemicals in the Cyclic Aliphatic Bromide Cluster pose unreasonable risks that must be regulated under TSCA, a change from the draft evaluation which found none of the evaluated uses meet the statutory threshold for regulation.

The chemicals, which are banned under the Stockholm Convention, a global chemical treaty to which the United States is not a party, have been used as flame retardants in expanded polystyrene (XPS) and extruded polystyrene (EPS) in insulation foam used for construction.

Breast Cancer Coalition Addresses Dangers of PFAS Chemicals

Grady Culhane, CapeCod.com

<https://www.capecod.com/newscenter/breast-cancer-coalition-discussed-dangers-of-pfas-chemicals/>

HYANNIS – The Massachusetts Breast Cancer Coalition recently hosted a panel to discuss Per- and polyfluoroalkyl (PFAS) chemicals in food packaging.

The pane, “PFAS in Food Packaging: What You Should Know and What You Can Do”, discussed the prevalence of the material in food packaging, current regulations surrounding its use, and how states and retailers are responding to it, and how people can reduce their exposure.

The discussion featured experts including Dr. Arlene Blum, Executive Director of Green Science Policy Institute; Dr. Maricel Maffini, Environmental Health Scientist and Dr. Laurel Schaider, Research Scientist with Silent Spring Institute.

PFAS are classified as “forever chemicals” that can be found in a variety of consumer products ranging from stain-resistant carpets to grease-proof food packaging.

“The chemicals in these families, sometimes they’re important so we don’t say ‘never use them’, but say ‘is it necessary’. Is it worth it, is there a safe alternative,” said Dr. Blum in the discussion.

The chemicals have been linked to a wide range of health issues including immune system toxicity, elevated cholesterol, delayed mammary gland development, effects on the thyroid and liver, and cancer, according to MBCC.

PFAS chemicals can be consumed through a variety of different food packaging or contaminated drinking water.

Blum said that some microwave popcorn is an example of a source of PFAS, as the popcorn bags occasionally use the material.

The chemicals also never break down in the environment, though Dr. Blum said it does have its positive uses, such as in water and oil-repellents.

The ban recently supported by Plymouth/Barnstable State Senator Susan Moran would disallow PFAS substances from being used for materials in food packaging.

More information on the chemical as well as alternative products that do not use the material can be found on pfascentral.org, said Blum.

Minnesota sets June 30 cutoff date for dicamba, will follow federal registration label usage

AGweek Staff Reports, AGWeek

<https://www.agweek.com/business/agriculture/6801977-Minnesota-sets-June-30-cutoff-date-for-dicamba-will-follow-federal-registration-label-usage>

New federal label requirements for the products include a June 30 cutoff date, requirement of an approved pH-buffering agent to be mixed with products prior to all applications, requirement of a downwind buffer in areas where listed endangered species are located and additional recordkeeping items.

The Minnesota Department of Agriculture announced this month it will follow federal registration and label usage for the herbicide dicamba on dicamba-tolerant soybeans in Minnesota for the 2021 growing season.

The U.S. Environmental Protection Agency announced in October it registered XtendiMax with VaporGrip Technology by Bayer, Engenia by BAS and Tavium Plus VaporGrip Technology by Syngenta with new control measures to curb alleged off-site movement issues like spray drift and/or volatilization.

For the last two years, the MDA placed an annual June 20 cutoff date on registered dicamba products based on research and pesticide misuse complaints. The cutoff date was not included on the federal label, but to curb off-site movement, the EPA has now limited states' abilities to impose further application restrictions.

The new federal label requirements for the products include:

An application cutoff date of June 30, unless growth stage cutoff comes first.

Requiring an approved pH-buffering agent, also known as a volatility reducing agent, be tank mixed with dicamba products prior to all applications.

Requiring a downwind buffer of 240-feet and 310-feet in areas where listed endangered species are located.

Additional recordkeeping items.

In addition to the June 30 cutoff date, Xtendimax and Tavium have crop growth stage cutoffs.

The MDA is also requiring product makers provide approved education and training of applicators and provide more Minnesota-specific data on the use of dicamba to inform future department decisions.

"Dicamba is an important tool for combating herbicide-resistant weeds in dicamba-tolerant soybeans," said Thom Petersen, commissioner of agriculture. "However, it's also important to limit impacts on neighboring homes, farms, and gardens. It will be necessary for applicators to understand and follow new label language including complete record-keeping requirements."

Since dicamba was first registered for use on dicamba-tolerant soybeans in the 2017 growing season, the MDA has fielded complaints each year of alleged off-site movement onto neighboring property. The annual totals of complaints were: 2017: 253 reports; 2018: 53 reports; 2019: 22 reports; 2020: 124 reports.

Petersen said it is important for farmers to understand the department will "increase our enforcement of the use of these products by examining application records."

"We believe that additional training will help ensure the label is being followed," said Petersen. "We also look forward to working with the University of Minnesota on research to better understand how these products can move off target. Our ability to gather as much data as we can on these products is critical for their continued use in the future."

Restricted-use pesticides

In Minnesota, the XtendiMax, Engenia, and Tavium formulations of dicamba are approved for use on dicamba tolerant soybeans only and are "Restricted Use Pesticides" for retail sale to and for use only by certified applicators.

Pesticide product registrations are renewed on an annual basis in Minnesota.

Trump administration punts on protections for monarch butterfly

Rachel Frazin, The Hill

<https://thehill.com/policy/energy-environment/530298-trump-administration-punts-on-protections-for-monarch-butterfly>

The Trump administration on Tuesday declined to give the monarch butterfly protections for threatened species for now, but left the door open for protections in the future.

The Fish and Wildlife Service (FWS) determined that adding the butterfly to the list of threatened and endangered species was “warranted” but that it is unable to do so because it needs to devote its resources to higher-priority species.

The FWS said that its “warranted-but-precluded” determination means that every year it will consider adding the butterfly to the list until it decides to propose listing it or determines that protections aren’t warranted.

“We conducted an intensive, thorough review using a rigorous, transparent science-based process and found that the monarch meets listing criteria under the Endangered Species Act,” said FWS Director Aurelia Skipwith.

The agency determined that 161 species that are on the waiting list for protections, or 64 percent of species on the list, are a higher priority than the monarch.

According to FWS, North American monarch populations have declined over the past 20 years. The eastern portion of the population fell from about 384 million in 1996 to 60 million in 2019, and the western portion fell from 1.2 million in 1997 to fewer than 30,000 last year.

The decision came after a 2014 [petition](#) from environmental groups seeking threatened species status for the butterfly.

The groups argued at the time that among the threats to the species is the loss of the milkweed plant that the butterflies are dependent on and particularly linked that decline to the use of the pesticide glyphosate. Glyphosate is a key ingredient in the Roundup weedkiller, which lawsuits have linked to non-Hodgkin's lymphoma, though the company behind the product has maintained that it is safe to use.

Other factors that the groups said harmed the species include climate change and severe weather events, as well as invasive species.

“Climate change has impacted both those populations but especially in Mexico it's been getting warmer and warmer, so when the butterfly should be ... building their fat storage to make the migration north, [but] because it's getting warmer and warmer, they're flying around a lot more and burning the reserve they need to make epic migration back north,” Stephanie Kurose, an endangered species policy specialist with the Center for Biological Diversity, told The Hill.

And advocates argued that the butterflies need protection sooner rather than later.

“Protection for Monarchs is needed — and warranted — now,” said George Kimbrell, legal director at the Center for Food Safety, in a statement. “The Biden administration must follow the law and science and protect them.”

'Habitat' defines a heated new debate over protections

Michael Doyle, E&E News

<https://www.eenews.net/greenwire/2020/12/15/stories/1063720739>

Prompted in part by the travails of the dusky gopher frog, the Fish and Wildlife Service and NOAA Fisheries today finalized a formal definition of “habitat” for use under the Endangered Species Act.

Though it sounds both routine and technical, the definition will help guide and perhaps limit crucial future decisions on designating critical habitat for protected species.

The **final definition**: “For the purposes of designating critical habitat only, habitat is the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.”

No current critical habitat designations will be reevaluated as a result of the definition. FWS says the definition is broad enough to encompass both occupied and unoccupied critical habitat but that questions about whether an unoccupied area qualifies as habitat are less likely to occur.

"Given that this will improve implementation of the Endangered Species Act and how stakeholders engage with it, we are very happy to announce this final definition of habitat," FWS Director Aurelia Skipwith said in a statement.

Skeptics, though, raise warning flags about the implications.

"This new definition unambiguously closes the door to designating many types of unoccupied areas that would have previously qualified as critical habitat," Ya-Wei Li, director for biodiversity with the Environmental Policy Innovation Center, said in an email.

Li added that "the new definition is problematic because one purpose of critical habitat is to help protect areas that a species will need in the future to adapt to climate change and other shifts in its environment."

The final definition differs from two alternatives proposed by the federal agencies earlier this year ([Greenwire](#), July 31).

"We received numerous comments that the proposed and alternative definitions lacked clarity, were ambiguous, and used terms that needed to be defined further," the agencies noted. "Additionally, commenters identified specific issues with some of the terms used ... and were concerned overall that the definition could have unintended consequences."

Critical habitat is that deemed "essential for the conservation of the species."

Any federal agency seeking to authorize, fund or carry out an action on designated land must first consult with FWS to ensure that the action is "not likely to ... result in the destruction or adverse modification of critical habitat."

Dusky gopher frog

In 2012, FWS included more than 1,500 acres of private land in Louisiana in its designation of critical habitat for the dusky gopher frog. FWS and consulting scientists identified the property as having the type of ephemeral ponds essential to the frog's well-being ([Greenwire](#), Nov. 27, 2018).

The frog used to be found throughout coastal Alabama, Louisiana and Mississippi, but most individuals now live around a single pond in Mississippi. The Louisiana landowners argued that the 1,544 unoccupied acres doesn't qualify as critical habitat because the land would need restoration to be useful.

In a 2018 Supreme Court decision, Chief Justice John Roberts observed that the Endangered Species Act does not provide a "baseline definition" of habitat.

"It identifies only certain areas that are indispensable to the conservation of the endangered species," Roberts wrote. "The definition allows the [Interior] Secretary to identify the subset of habitat that is critical, but leaves the larger category of habitat undefined."

The federal government and the landowners subsequently reached a settlement. The Trump administration issued final rules for the ESA last year but didn't address the broader habitat definition.

"This is yet another blow to endangered species from an administration that subscribes to a 'death by a thousand cuts' approach to bedrock wildlife laws," said Jamie Rappaport Clark, president and CEO of Defenders of Wildlife, adding that "we will ask the Biden administration to right this wrong."

Cleaning Product Enforcement Challenge Highlights Reach of EPA's Antimicrobial Regulatory Authority

Kelley Drye & Warren LLC, JD Supra

<https://www.jdsupra.com/legalnews/cleaning-product-enforcement-challenge-91499/>

For years, EPA has asserted broad authority to regulate products that are labeled or marketed with express or implied pesticidal (including antimicrobial) claims. During the current pandemic, that authority has been exercised aggressively, particularly against products, many of which are imported, that claim or suggest effectiveness in fighting coronavirus and other microbes. A novel litigation challenge to one such EPA enforcement action provides a timely reminder of the extensive scope of the authority claimed by the agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Zuru, LLC, filed suit in September alleging that EPA incorrectly declared their product, Bactive Heavy Duty Cleaning Wipes, to be an unregistered “pesticide” and blocked its import into the United States. The crux of the case is that Zuru asserts that it does not make any “disinfectant or other pesticidal claims” for the product, which it says is labeled only “as intended for use in heavy duty cleaning of nonporous surfaces to fight the presence of dirt, grease, and common messes.”

For several reasons, however, EPA contends that the cleaning wipes are pesticide products regulated under FIFRA. In particular, the agency argues that the wipes fall under EPA’s FIFRA authority because they contain an active ingredient (chlorhexidine digluconate) found in a number of other EPA-registered disinfectants. Moreover, while no express pesticidal claims are made on the product packaging, EPA alludes to statements made on-line by third party resellers that the wipes are “disinfectants” and “kill germs.” The agency also contends that the very name “‘Bactive’ implies bacterial fighting properties.”

The case, for which EPA earlier this week was granted a 10-week extension to respond, provides compelling lessons for companies that sell cleaning products to keep in mind, including:

- (1) The scope of FIFRA is not limited to express pesticidal claims made on the product label or in marketing materials. In determining whether a product is “intended for a pesticidal purpose,” EPA will look beyond express claims to examine whether labeling, ingredients, marketing materials, and even the product name imply pesticidal intent.
- (2) EPA can regulate a product for which no pesticidal claims are made if it contains a substance that “has no significant commercially valuable use other than as a pesticide.” This is the core issue in the Zuru case, in which the company argues that the ingredient at issue also has separate value as a cleaning agent.
- (3) Sometimes, an ingredient or product becomes commonly associated with “pesticidal” purposes, such that EPA asserts regulatory authority over it even absent other express or implied pesticidal claims. The classic example, from decades ago, is Avon’s Skin So Soft lotion that was not overtly marketed as a pesticide, but became commonly associated in the public mind with mosquito repellency. Third party website testimonials and the statements of product resellers, such as in the Zuru case, may be cited as evidence of pesticidal intent based on public perception.
- (4) Product names and logos can be considered to be “pesticidal” claims. This seems to be a major hurdle for Zuru in its case, as the agency asserts regarding the term “Bactive.”

While the parties may reach a settlement, the case is worth keeping a close eye on for its potential to shape the scope of EPA’s FIFRA authority as applied to cleaning products and other disinfectants/antimicrobials.

The case is *Zuru, LLC v. EPA, et al.*, in the United States District Court for the District of Columbia.

EPA Publishes Draft Compliance Guide Addressing Surface Coatings under PFAS SNUR

The National Law Review

<https://www.natlawreview.com/article/epa-publishes-draft-compliance-guide-addressing-surface-coatings-under-pfas-snur>

On December 10, 2020, the U.S. Environmental Protection Agency (EPA) announced the availability of a draft compliance guide that outlines which imported articles are covered by EPA’s July 2020 final significant new use rule (SNUR) that prohibits companies from manufacturing, importing, processing, or using certain long-chain per- and

polyfluoroalkyl substances (PFAS) without prior EPA review and approval. The draft guide will be “the official compliance guide for imported articles that may contain long-chain perfluoroalkyl carboxylate chemical substances as part of a surface coating.” According to EPA, the draft guide provides additional clarity on what is meant by a “surface coating”; identifies which entities are regulated; describes the activities that are required or prohibited; and summarizes the notification requirements of the final SNUR. EPA intends to publish a notice in the *Federal Register* announcing the availability of the draft guidance and beginning a 30-day comment period.

Background

On July 27, 2020, EPA promulgated a final SNUR for long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances. 85 Fed. Reg. 45109. EPA first proposed a SNUR for LCPFAC and perfluoroalkyl sulfonate chemical substances on January 21, 2015. 80 Fed. Reg. 2885. On March 3, 2020, EPA issued a proposed supplemental SNUR for LCPFAC chemical substances that would make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles. 85 Fed. Reg. 12479. The final SNUR requires persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of these chemical substances for the significant new uses described in the notice. The required significant new use notification initiates EPA’s evaluation of the conditions of use associated with the significant new use. Manufacturing (including import) or processing for the significant new use are prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. EPA notes that as with any SNUR, the final rule excludes ongoing uses as ongoing uses cannot be subject to a SNUR. The final rule was effective on September 25, 2020.

EPA states that the March 2020 proposed supplemental SNUR was intended “to be responsive to the article consideration provision” under Section 5(a)(5) of the Toxic Substances Control Act (TSCA), which was added by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act). Section 5(a)(5) states that articles can be subject to notification requirements as a significant new use provided that EPA makes an affirmative finding in a rule that the reasonable potential for exposure to a chemical from an article or category of articles justifies notification. More information on the proposed supplemental SNUR is available in our February 28, 2020, memorandum, “Proposed Supplemental SNUR Would Remove Exemption for LCPFAC Chemical Substances Used as Surface Coatings on Articles.”

The final SNUR will require persons to notify EPA at least 90 days before commencing:

- The manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015;
- The manufacturing (including importing) or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015 (the date of the original proposed SNUR);
- The import of a subset of LCPFAC chemicals as part of a surface coating on articles; and
- The import of perfluoroalkyl sulfonate chemical substances as part of carpets.
- The final SNUR will preclude the commencement of such manufacturing and processing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. More information is available in our July 27, 2020, memorandum, “EPA Issues Final SNUR for LCPFAC and Perfluoroalkyl Sulfonate Chemical Substances.”

Draft Compliance Guide

The draft compliance guide is intended to assist companies that import LCPFAC chemical substances as part of a surface coating on articles. According to EPA, many of the following types of businesses may be covered by the draft guide:

- Manufacturers (including importers) of one or more of subject chemical substances (North American Industrial Classification System (NAICS) codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries;
- Fiber, yarn, and thread mills (NAICS code 31311);
- Carpet and rug mills (NAICS code 314110);
- Home furnishing merchant wholesalers (NAICS code 423220);
- Carpet and upholstery cleaning services (NAICS code 561740);
- Manufacturers of computer and other electronic products, appliances, and components (NAICS codes 324 and 335);
- Manufacturers of surgical and medical instruments (NAICS 339112);

- Merchant wholesalers (NAICS codes 423 and 424);
- Stores and retailers (NAICS codes 442, 443, 444, 448, 451, and 454); and
- Providers of other support services (NAICS code 561990).

Guidance for Articles Subject to the SNUR

What Is an Article

The draft compliance guide states that as defined at 40 C.F.R. Section 704.3, “article means a manufactured item: (1) which is formed to a specific shape or design during manufacture; (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.” According to the draft guide, an imported article must have an end-use function dependent in whole or in part upon a shape or design that was present at the point of import. If the shape and design of an item at the point of import does not serve any function with respect to the item’s end use, then the item being imported is not an article. EPA provides the following example:

Plastic or metallic blocks or sheets imported and then processed in such a way that they entirely lose the shape they had at the point of import (*e.g.*, by being melted down, molded, extruded, cut up extensively or into small pieces, or further reacted) would not qualify as articles at the point of importation. Conversely, if plastic or metallic sheeting is imported with a specific thickness, the sheeting may still be considered an imported article even though the expected end use of the sheeting may involve cutting or trimming to a different length or width. However, there must still be a relationship between the shape or design of the sheeting and the end use of the sheeting.

Examples of Articles Subject to the SNUR

The draft compliance guidance states that because the LCPFAC SNUR is for significant new uses, the following is a non-exhaustive list of potential articles that may use LCPFAC chemical substances as part of a surface coating on the article:

Apparel	Electronic components
Outdoor equipment	Light bulbs
Automotive parts	Solar panels
Carpets	Paper goods
Furniture	Luggage
Construction materials	

What Is Not an Article

The draft compliance guide states that products such as paints, lubricants, and fire-fighting foam are not articles. A paint, however, would be considered as part of an article if applied to an article (*e.g.*, paint on a car is considered as part of an article but paint in a can is not an article under TSCA). Additionally, according to the draft guide, a lubricant applied to an article would be considered as part of an article. The draft compliance guide provides the following example:

A lubricant such as automotive grease would be considered part of an article when already included within an automobile’s engine. When automotive grease is purchased by a consumer at a car supply store to add to the automobile, that automotive grease would not be considered an article.

What Is a Surface Coating?

According to the draft compliance guide, a coating is a material applied in a thin layer to a surface as a protective, decorative, or functional film. The draft guide notes that the term “coating” often refers to paints such as lacquers or enamels, but states that it also refers to films applied to other materials, including, but not limited to, paints, varnishes, sealants, adhesives, inks, maskants, and temporary protective coatings.

The draft guide states that during the public comment period for the 2020 proposed supplemental SNUR, several commenters asked EPA to define “surface coating” and to include a definition in the regulatory text of the rule. EPA

declined to do so, but instead “is providing additional clarity on what is meant by a ‘surface coating’ in this guidance document.” The draft compliance guide provides the following example:

If Chemical A is used in furniture varnish that is applied during the production of a piece of furniture at a furniture manufacturer, once Chemical A is applied to the furniture, Chemical A is considered a surface coating that is part of an article. If a varnish containing Chemical A is purchased at a hardware store, for use by a consumer to build or refinish a piece of furniture, the container of varnish containing Chemical A could be used as a surface coating but not be considered as part of an article.

What Constitutes a Surface Coating Subject to the SNUR?

In the context of the LCPFAC SNUR, EPA considers any LCPFAC from the list in Table 1 of the draft compliance guide or perfluorooctanoic acid (PFOA) and its salts that meets one of the following two criteria to be a surface coating covered by the SNUR:

Coating on any surface of an article that is in direct contact with humans or the environment during the article’s normal use or reuse, whether the coating is oriented towards the interior or exterior of the article; or

Coating on any internal component, even if facing the interior of the article, if that component is in contact with humans or the environment during the article’s normal use or reuse.

The draft compliance guide provides the following example:

An importer of luggage is working with a foreign manufacturer to develop a new product line of fabric luggage. To protect the luggage against water and stains, the importer would like a surface coating protectant applied to the luggage. The foreign manufacturer has three coatings they can use: one with Chemical A, another with Chemical B, and another with Chemical C. All three chemicals are LCPFAC chemical substances, so the importer must ensure that he complies with the final LCPFAC SNUR. While all three chemical substances are LCPFAC chemical substances, they are not all subject to the same requirements of the final SNUR.

Chemical A is Chemical Abstracts Service Registry Number (CASRN) 17741-60-5, which is listed in Table 1 - LCPFAC Chemical Substances Subject to Reporting After December 31, 2015. Because it is listed in Table 1 and there is no ongoing use for Chemical A under 40 C.F.R. Section 721.10536(b)(5), Chemical A is subject to the LCPFAC SNUR when imported in an article as part of a surface coating. If the importer wishes to import luggage containing Chemical A as a surface coating, they must first submit a SNUN at least 90 days before they intend to commence import.

Chemical B is CASRN 27905-45-9, which is also listed in Table 1 -- LCPFAC Chemical Substances Subject to Reporting After December 31, 2015. Chemical B has an ongoing use pursuant to 40 C.F.R. Section 721.10536(b)(5)(ii), however, for use “as a coating or component of a hydrophobic and/or oleophobic coating or barrier applied to manufactured articles or component of articles using an energy source or plasma deposition methods, which include a pulse deposition mode. Examples of such articles include: electronic devices and components thereof, medical consumables and bio-consumables, filtration devices and filtration materials, clothing, footwear and *fabrics*.” Because the use of Chemical B as a coating on fabric is recognized as an ongoing use in the final SNUR, this use of Chemical B is not a significant new use subject to the final SNUR. The foreign manufacturer may use CASRN 27905-45-9 as a surface coating on the fabric luggage without the importer needing to submit a SNUN.

Chemical C is CASRN XXXX-XX-X (a hypothetical chemical for this example), which is a LCPFAC chemical substance subject to the final SNUR pursuant to 40 C.F.R. Section 721.10536(b)(1). Chemical C is not listed in Table 1 - LCPFAC Chemical Substances Subject to Reporting After December 31, 2015 and it is not PFOA or a PFOA salt. Only LCPFAC chemical substances that are listed in Table 1 or that are PFOA and its salts are subject to the notification requirements of 40 C.F.R. Section 721.25 when imported as part of a surface coating of an article (*see* 40 C.F.R. Section 721.10536(c)(1)). As such, when imported as part of a surface coating of an article, Chemical C is not subject to the rule and may be used by the foreign manufacturer as a surface coating on the fabric luggage and then imported into the US without the importer

needing to submit a SNUN. Chemical C may be subject to the SNUR if manufactured, imported, or processed for another use, however.

Surface Coatings That Have Cured or Undergone Chemical Reaction after Application

A question arose as to the application of the SNUR to surface coatings that have cured post-application. According to the draft compliance guide, articles that have surface coatings that contain certain LCPFAC chemical substances that have been cured or undergone chemical reaction after being applied to an article are subject to the SNUR.

Complex Durable Goods

The draft compliance guide states that complex durable goods are subject to the SNUR. TSCA Section 6(c)(2)(D) defines the term “complex durable good.” The draft guide states that statutory exemptions for replacement parts for complex durable goods may be granted pursuant to TSCA Section 6(c)(2)(D) in some cases, but only in TSCA Section 6(a) risk management rules. Designation as a “complex durable good” under TSCA Section 6 does not affect whether a use is or is not a significant new use under the SNUR. According to the draft compliance guide, “EPA acknowledges that imported articles may be comprised of multiple components and have a complex supply chain, which may present greater demands on some importers to ensure that if an article contains certain LCPFAC chemical substances in surface coatings, a SNUN is submitted to EPA [at] least 90 days before engaging in import.”

An Article Containing an LCPFAC Chemical Substance as a Surface Coating Where the LCPFAC Chemical Substance Is Believed Not to Be Released

The draft compliance guide states that if an article contains an LCPFAC chemical substance as a surface coating, but the LCPFAC chemical substance is believed not to be released, the article is subject to the SNUR. According to the draft guide, in the final SNUR, EPA affirmatively found that under TSCA Section 5(a)(5) that the notification for import is justified due to the reasonable potential for exposure to certain LCPFAC chemical substances when part of surface coatings on articles. The article is subject to the SNUR regardless of whether the *importer* believes that no release or exposure will result from an imported article containing a subject LCPFAC chemical substance as part of a surface coating, unless that given use is listed as an ongoing use at 40 C.F.R. Section 721.10536(b)(5). To import an article containing certain LCPFAC chemical substances in surface coatings, a SNUN needs to be submitted to EPA at least 90 days before importation occurs. The submission of a SNUN allows EPA to evaluate potential uses (before those uses would begin) for any hazards, exposures, and risks that might exist.

Impurities in Surface Coatings

The draft compliance guide states that impurities in surface coatings are not subject to the SNUR. To the extent the chemical substance subject to the SNUR is only “unintentionally present” at the point of foreign manufacture, it is exempt from reporting by the importer as an imported impurity (see 40 C.F.R. Section 721.45(d)). As such, importers are not required to submit a SNUN for a substance based simply on that substance’s presence as an impurity (*i.e.*, a chemical substance is unintentionally present with another chemical substance (40 C.F.R. Section 720.3(m))). If a subject LCPFAC chemical substance is only present as an impurity in a surface coating as part of an article, then it is not subject to the SNUR.

Processors of Articles

According to the draft compliance guide, processors of articles are not subject to the SNUR. The draft guide states that EPA is retaining the exemption at 40 C.F.R. Section 721.45(f) for persons who process chemical substances as part of articles because existing stocks of articles still contain LCPFAC or perfluoroalkyl sulfonate chemical substances. Because the processing of articles containing LCPFAC or perfluoroalkyl sulfonate chemical substances is ongoing, it cannot be subject to a SNUR. The draft guide notes that EPA considers recycling to be a form of processing.

Who Must Comply

According to the draft compliance guide, an importer of articles is subject to the SNUR if he/she imports, for a “significant new use,” articles containing a subset of LCPFAC chemical substances as part of a surface coating. The subset of LCPFAC chemical substances for which EPA lifted the articles exemption includes those listed in Table 1 of the draft guide and PFOA or its salts.

The draft compliance guide states that use of the subject LCPFAC chemical substances as part of food packaging or medical devices is not subject to the rule. TSCA Section 3(2)(B) excludes any food, food additive, drug, cosmetic, or device regulated under the Federal Food, Drug, and Cosmetic Act from the definition of a chemical substance under TSCA. The U.S. Food and Drug Administration (FDA) has separately issued restrictions on the use of PFAS chemical substances in FDA regulated uses, however. The draft guide suggests that prior to import, importers should ensure that they are in compliance with all federal and state regulations regarding PFAS chemical substances.

The final SNUR included amendments requiring persons to notify EPA at least 90 days before commencing: the manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015; the manufacturing (including importing) or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015 (the date of the original 2015 proposal); and the import of perfluoroalkyl sulfonate chemical substances as part of carpets. EPA notes that these additional amendments “are not the subject of this compliance guide,” however.

Commentary

In response to comments on the 2020 supplemental proposed rule that asked EPA to define “surface coating” in the final SNUR, EPA chose not to define the term and stated that it would address the subject within a reasonable time. EPA stated that it “is not defining this term due to the many different ways that LCPFAC chemical substances could be applied to an article as part of a surface coating and how a given article could move through the supply chain from manufacture to disposal.” 85 Fed. Reg. at 45114. The draft guidance is a step in the implementation of that commitment. EPA’s decision to seek comment on the draft guidance is to be commended. It will be especially welcomed by potentially regulated entities and help inform and improve the final guidance when issued in final. We question whether the 30-day public comment period is sufficient, however, given the holiday season as well as the COVID-19 public health crisis as the guidance raises many significant issues.

For example, and as noted above, the draft guidance states that in the context of the LCPFAC SNUR, EPA considers any LCPFAC from the list in Table 1 of the draft compliance guide or PFOA and its salts that meets one of the following two criteria to be a surface coating covered by the SNUR:

Coating on any surface of an article that is in direct contact with humans or the environment during the article’s normal use or reuse, whether the coating is oriented towards the interior or exterior of the article; or

Coating on any internal component, even if facing the interior of the article, if that component is in contact with humans or the environment during the article’s normal use or reuse.

Additional explanation of what “contact with the environment” means in these criteria under the draft guidance may be useful to the potentially regulated community. For example, does it mean any exposure to air or not totally enclosed?

In explaining in the draft guidance what an “article” is under SNUR, EPA refers to the definition of “article” in the TSCA Section 8(a) reporting and recordkeeping regulations at 40 C.F.R. Section 704.3. As the definition of “article” in the premanufacture notification regulation at 40 C.F.R. Section 720.3 appears applicable to the SNUR given 40 C.F.R. Section 721.3, which, in turn, refers to the definitions at 40 C.F.R. 720.3, and the regulations at 40 C.F.R. Sections 721.9582(a) and 721.10536(a) state that the definitions at 40 C.F.R. Section 721.3 apply, EPA’s reference to 40 C.F.R. Section 704.3 for purposes of the guidance thus *appears* to be in error. The definitions of “article” at 40 C.F.R. Section 720.3 and 40 C.F.R. Section 704.3 are substantially similar, however. The draft guidance merits a disciplined review, thoughtful comment, and a longer comment period.

EPA Releases Final Risk Evaluation for Perchloroethylene, Finds Almost All Conditions of Use Present Unreasonable Risks to Workers, ONUs, Consumers, and Bystanders

Lynn L. Bergeson & Carla N. Hutton, Bergeson & Campbell TSCA Blog

<http://www.tscablog.com/entry/epa-releases-final-risk-evaluation-for-perchloroethylene-finds-almost-all-c>

On December 14, 2020, the U.S. Environmental Protection Agency (EPA) released the final risk evaluation for perchloroethylene. The final risk evaluation determined that there are unreasonable risks to workers, occupational non-users (ONU), consumers, and bystanders from 59 out of 61 conditions of uses:

- Consumers and Bystanders: EPA found unreasonable risks to consumers and bystanders from all consumer uses of perchloroethylene. Common consumer uses include as a dry cleaning solvent; in cleaning and furniture care products; automotive care products like brake cleaners, lubricants, and greases; and adhesives in arts and crafts. The risk to consumers from perchloroethylene's use in dry cleaning is from short-term skin exposure to items cleaned with perchloroethylene; and
- Workers and ONUs: EPA found unreasonable risks to workers from all but two occupational uses of perchloroethylene. Additionally, EPA found unreasonable risks from most commercial uses of perchloroethylene to workers nearby but not in direct contact with perchloroethylene (known as ONUs). This includes an unreasonable risk to workers and ONUs when domestic manufacturing or importing perchloroethylene; processing as a reactant and intermediate; incorporation into cleaning and degreasing products; uses in a variety of industrial and commercial applications such as degreasing, dry cleaning, in adhesives and sealants, and in paints and coatings; and disposal. The primary health risk identified in the final risk evaluation is neurological effects from short- and long-term exposure to perchloroethylene. The conditions of use in the final risk evaluation that EPA determined do not present an unreasonable risk are distribution in commerce and industrial and commercial use in lubricants and greases for penetrating lubricants and cutting tool coolants.

EPA found no unreasonable risks to the environment. The next step in the process required by the Toxic Substances Control Act (TSCA) is developing a plan to address the unreasonable risks identified in the final risk evaluation. EPA states that it "is moving immediately to risk management for this chemical and will work as quickly as possible to propose and finalize actions to protect against the unreasonable risks." Potential actions EPA could take to address these risks include regulating how perchloroethylene is used or limiting or prohibiting the manufacture, processing, distribution in the marketplace, use, or disposal of perchloroethylene, as applicable. EPA notes that as with any chemical product, it "strongly recommends that users of products containing perchloroethylene continue to carefully follow all instructions on the product's label and safety data sheet." More information will be available in a forthcoming memorandum that will be posted on our website.

Monarch Butterflies Struggle as Feds Delay Protection

Sylvia Fallon, NRDC Blog

<https://www.nrdc.org/experts/sylvia-fallon/monarchs-butterflies-struggle-feds-delay-protection>

In response to a petition filed six years ago, the U.S. Fish and Wildlife Service just announced that monarch butterflies qualify for protections under the Endangered Species Act. . . but that they will not provide those protections now due to other priorities (also known as a 'warranted but precluded' finding).

In the last six years, many voluntary efforts have been made to help boost monarch populations—including milkweed planting (the plant that monarchs need to reproduce) at the federal and state level as well as numerous private sector initiatives. However, despite these efforts, monarchs continue to struggle with the western population nearing imminent extinction and the eastern population continuing to hover at dangerously low numbers. Now the butterflies will have to wait even longer to receive more help.

Monarch butterflies have long been a constant presence of many people's summer experience as the butterflies travel yearly from the forests of Mexico northward across the United States before heading back to Mexico each fall. Once

abundant, monarchs numbered up to nearly 1 billion, and generations of kids and teachers enjoyed raising them in their classrooms and learning about their life cycle. But over the course of last two decades, the number of monarch butterflies has plummeted by more than 85%. This decline has coincided with the introduction of genetically modified crops that are resistant to the application of glyphosate, commonly known as Roundup, which has allowed for the eradication of milkweed in the agricultural Midwest—an area that is key to the monarch’s migration. While other factors like climate change, other nectar sources, and the condition of their overwintering habitat in Mexico may also contribute to the decline, the loss of milkweed is one of the leading factors.

Monarchs are capable of rebounding, but in order to do so they need the right conditions—including abundant milkweed and other nectar sources. In addition to planting milkweed and other pollinator habitat, we need to scale back the use of agricultural pesticides like glyphosate, Enlist Duo, Dicamba and neonicotinoids—all of which are pervasive in traditional agriculture these days. There is a burgeoning movement by some farmers to move towards regenerative agricultural practices that work with nature instead of against it. This is the direction we need to be heading in. As people, we are dependent on farming and agriculture for the production of our food. But our food is dependent on insects such as pollinators like monarch butterflies and bees. We have to support solutions that allow both farming and biodiversity to thrive.

Today’s decision is an acknowledgement that monarch butterflies are in serious trouble, but it also delays critically needed action to help rescue the species. An Endangered Species Act listing would require the U.S. Fish and Wildlife Service to develop a coordinated plan for the recovery of monarch butterflies. It is plain to see that efforts over the past six years have not been enough to secure the population, and we will need to do much more if we want to ensure that future generations of kids can continue to experience the joy and wonder of watching monarchs migrate across our country each year.

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